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# Good Evidence Practice
## Building stakeholder trust in use of health data

Deloitte Centre
for Health Solutions

# Building stakeholder trust in the use of health data to generate real world evidence for the benefit of patients

Healthcare payers, including national governments, continue to face enormous cost and capacity challenges largely as a result of increasing demand from growing numbers of older people with multiple complex conditions and a rise in the incidence of non-communicable lifestyle diseases such as diabetes. Treatment costs are rising alongside this increase in demand partly due to the challenges inherent in developing products which are targeted at complex disease states and patient sub-populations. In order to continue delivering the best possible outcomes for patients, it is vital that new ways are found to enable therapeutics to be brought to market at a sustainable cost.

## The opportunity

Healthcare data present a unique opportunity to develop real world evidence insights into existing diagnostic and treatment pathways, to identify unmet need, and to demonstrate the actual clinical and economic impact of interventions within the healthcare system. This evidence enables R&D organisations to prioritise their pipeline investments more effectively, better understand underlying causes of disease and identify opportunities for indication expansion and business development. It allows commercial organisations to demonstrate the clinical and economic value of their products to payers, to deploy health solutions that truly integrate healthcare and therapeutics and to build new reimbursement mechanisms.

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The development of real world evidence is therefore essential to sustain improvements in patient outcomes – yet there are significant privacy concerns regarding the sharing and use of health data for this and other purposes. Transparency and communication of the benefits of real world evidence is essential but insufficient alone to reassure sceptics. In order to build further trust across all stakeholder groups, including patients, payers, providers, clinicians, academics, regulators and the pharmaceutical industry, a mutually accepted process with governance is required for the use of health data to generate real world evidence.

Good Clinical Practice (GCP) is an established and successful standard that gives the confidence necessary for clinicians to prescribe and patients to follow treatments developed through clinical trials. Given the acceptance of GCP, Deloitte believes that an analogous approach should be developed to guide real world evidence studies. We have termed this approach *Good Evidence Practice* (GEP).

## Good Evidence Practice

Taking inspiration from GCP, GEP would need to cover the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of real world evidence studies. In order to be effective, standards within the process would need to be mutually agreed based on current best practices and take into account the varying regulatory and market access requirements in different regions worldwide. Once in place, mutually agreed standards within the GEP process would require regulatory enforcement supported by appropriate penalties for non-compliance in order to ensure the credibility of real world evidence and the protection of patient confidentiality.

The confidence through an accepted, standardised process would benefit all stakeholders. The pharmaceutical industry would have a clear set of expectations to meet when generating real world evidence to demonstrate where a product can deliver enhanced outcomes in areas of unmet patient need. Payers and regulators would be able to place increased reliance on real world evidence studies and potentially gain access to new data on product efficacy and economy in non-experimental settings. In such a scenario patients would benefit from their healthcare providers being enabled to provide evidence based, optimised treatment regimes.

The value of real world evidence is strongly linked to the pool of data available for analysis. The broader the sample size, the more reflective the insights of the population as a whole. Given current widespread negative sentiment against the use of health data in real world evidence studies, the proposed GEP standard is intended as a way to engender confidence in stakeholders to allow the largest possible pool of health data to be used against a clear set of requirements for the generation of credible real world insights which in turn should act as a sustainable basis for improved patient outcomes.

If you are a stakeholder interested in discussing the GEP concept further please feel free to get in touch with one of the contacts listed on the back.

**References**

Measuring the return from pharmaceutical innovation 2013, Deloitte Centre for Health Solutions, December 2013.

See also www.deloitte.co.uk/centreforhealthsolutions

Trustworthy reuse of health data: A transnational perspective, Geissbuhler, A, *et al*. January 2013. Int J Med Inform. 2013 Jan; 82(1):1-9.

See also http://ichgcp.net/

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## Contact information

The Deloitte Centre for Health Solutions, part of Deloitte LLP, generates insights and thought leadership based on the keys trends challenges and opportunities within the healthcare and life sciences industry. Working closely with other centres in the Deloitte network, our team of researchers develop ideas, innovations and insights that encourage collaboration across the health value chain, connecting the public and private sectors, health providers and purchasers, consumers and suppliers. To learn more about the Deloitte Centre for Health Solutions, its projects and events, please visit:www.deloitte.co.uk/centreforhealthsolutions.

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